Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: December 8, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

ASG

SUBJECT: FW: Recall—Firm Press Release - Bayer Consumer Care Voluntarily Recalls One Lot of Combination Package of Alka-Seltzer plus Day and Night Cold Formula Liquid Gels

Single Lot Affected by Package Labeling Issue - The product was sold only in the U.S. at retail outlets nationwide.

Suggested Action: Consumers who purchased combination packages of Alka-Seltzer Plus Day and Night Cold Formula Liquid Gels from the lot included in this recall (details below) should stop using the product and contact Bayer with any questions or for instruction on a refund or replacement. Consumers should contact the Customers Call Center at 1-800-986-3307, Monday – Friday, 8:30 AM – 5:30 PM eastern standard time. Any consumer with a medical concern or questions should contact their healthcare provider. This is being provided for consumer inquiry.

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Morristown, NJ. – December 8, 2009 – In consultation with the U.S. Food and Drug Administration (FDA), Bayer's Consumer Care Division has begun a voluntary recall of a single product lot of the combination package of Alka-SeltzerPlus® Day and Night Cold formula Liquid gels. Bayer initiated the recall after identifying that the labeling on the foil blister card of certain packages within the lot (less than 4 percent) were printed with the label reversed. In a limited number of combination package of Alka-Seltzer Plus day and Night Cold Formula Liquid Gels from the lot listed below the information on the underside of the blister package was revered. Therefore, the label for the green Night product appears under some of the blue Day product and vice versa. As such, there is a risk that consumer may not be aware of the warning of an antihistamine in the product that could cause drowsiness. All individual liquid filled capsules are imprinted correctly.

The affect Alka Seltzer Plus product lot number can be found on both the interior blister package (in black text adjacent to the expiration date) as well as on the exterior carton contain the blister packaging (embossed on the side panel under the Bayer logo):

- Product Name: Alka-Seltzer Plus Day and Night Liquid Gels
- Package size: 20 liquid filled capsules per carton (12 day formulation capsules and 8 night formulation capsules)
- UPC#: 016500537779
- Lot #: 296939L
- Expiration: 5/11
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Media Contact: Tricia McKernan - 866-683-1126

FDA posts press releases and other notices of recalls and market withdrawals from the firmed involved as a service to consumers, the media and other interested parties. FDA does not endorse with the product or the company.